

Notice of Allowability

Application No.

10/538,499

Examiner

DOUGLAS M. WILLIS

Applicant(s)

BURNS ET AL.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 24 January 2011.
2. ☒ The allowed claim(s) is/are 1-10,15 and 16.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>01-28-11</u> . |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>07-21-05; 11-26-08</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input checked="" type="checkbox"/> Other <u>Correction of Inventorship under 37 CFR 1.48(b)</u> . |

/DOUGLAS M. WILLIS/
Examiner, Art Unit 1624

/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624

DETAILED ACTION

Status of the Claims / Priority

Claims 1-13 and 15-17 are pending in the current application. According to the Amendments to the Claims, filed January 24, 2011, claims 1 and 3 were amended and claim 14 was cancelled. This application is a 35 U.S.C. § 371 National Stage Filing of International Application No. PCT/AU2003/001661, filed December 11, 2003, which claims priority under 35 U.S.C. § 119(e) to US Provisional Application No. 60/483,399, filed June 26, 2003, and under 35 U.S.C. § 119(a-d) to AU 2002953255, filed December 11, 2002.

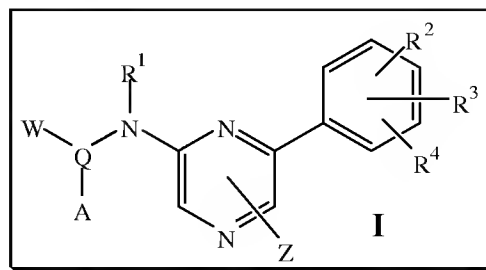
Correction of Inventorship Under 37 CFR 1.48(b)

In view of the papers filed January 24, 2011, the inventorship in this nonprovisional application has been changed by the deletion of Xianyong Bu, Harrison Sikanyika and Michael Francis Harte.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Status of Restrictions / Election of Species

Applicant's affirmation of the following election, without traverse, in the reply filed on December 29, 2009, is acknowledged: a) Group I - claims 1-10; and b) substituted pyrazine of formula I - p. 57, Table 1, example 8.



The requirement was made FINAL in the Non-Final Rejection, mailed on October 15, 2009.

Claim 1 is directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(b), claims 11-13 and 15-17, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement as set forth in the Office action, mailed on August 26, 2009, is hereby withdrawn. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicants are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. § 121 are no longer applicable. {See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971); and MPEP § 804.01}.

The sections of U.S.C. Title 35 that formed the basis of prior rejections formulated, as well as any references supporting said rejections, that are not included with this Office action, may be found in either the Non-Final Rejection, mailed October 15, 2009, the Final Rejection, mailed on March 22, 2010, or the Final Rejection, mailed on October 22, 2010. Furthermore, any rejections and/or objections of record not explicitly addressed herein below, are hereby withdrawn, in light of applicant's arguments, the Correction of Inventorship under 37 CFR

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1.48(b) and/or the Amendments to the Claims, filed January 24, 2011.

Thus, a fourth Office action and prosecution on the merits of claims 1-13 and 15-17 is contained within.

Reasons for Allowance

Claims 1-10, 15 and 16 are allowed.

The following is a statement of reasons for the indication of allowable subject matter:

The prior art is silent with respect to substituted pyrazines of the formula I, as recited in claim 1.

Consequently, the limitation on the core of the substituted pyrazines of the formula I that is not taught or fairly suggested in the prior art is W on the periphery of the pyrazine core. This limitation is present in the recited species of claim 9.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled Comments on Statement of Reasons for Allowance.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The following is a statement of examiner's amendment to the record:

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In claim 1, the text of line 1:

A compound of the formula

has been deleted and replaced with the following:

---“A compound of the formula I”---

In claim 1, the following text, with respect to W:

W is selected from C₂₋₄alkyl, C₂₋₆alkenyl; where C₁₋₄alkyl or C₂₋₆alkenyl may be

has been deleted and replaced with the following:

---“W is selected from C₂₋₄alkyl or C₂₋₆alkenyl, where C₂₋₄alkyl or C₂₋₆alkenyl may be”---

In claim 2, the text of line 1:

A compound according to claim 1 of formula II:

has been deleted and replaced with the following:

---“A compound of formula II:”---

In claim 2, the following text on page 4, with respect to A:

A is as defined in claim 1;

has been deleted and replaced with the following:

---“A is aryl or hetaryl each optionally substituted with 0-3 substituents independently selected from halogen, C₁₋₄alkyl, CF₃, aryl, hetaryl, OCF₃, OC₁₋₄alkyl, OC₂₋₅alkylNR¹⁸R¹⁹, Oaryl, Ohetaryl, CO₂R¹⁸, CONR¹⁸R¹⁹, NR¹⁸R¹⁹, C₁₋₄alkylNR¹⁸R¹⁹, NR²⁰C₁₋₄alkylNR¹⁸R¹⁹, NR¹⁸COR¹⁹, NR²⁰CONR¹⁸R¹⁹, NR¹⁸SO₂R¹⁹, where R¹⁸ and R¹⁹ are each independently H, C₁₋₄alkyl, C₁₋₄alkylcyclohetalkyl, aryl, hetaryl, C₁₋₄alkylaryl, C₁₋₄alkylhetaryl, or may be joined to form a 3-8 membered ring optionally containing an atom selected from O, S or NR²¹; R²⁰ is selected from H or C₁₋₄alkyl; and R²¹ is selected from H or C₁₋₄alkyl;”---

In claim 2, the text in line 4 on page 5, with respect to n:

n = 0-4;

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has been deleted and replaced with the following:

---“n is 0, 1, 2, 3 or 4;”---

In claim 2, the text of the last line on page 5:

W and prodrug are as defined in claim 1.

has been deleted and replaced with the following:

---“W is selected from C₂₋₄alkyl or C₂₋₆alkenyl, where C₂₋₄alkyl or C₂₋₆alkenyl may be optionally substituted with C₁alkyl, OH, OC₁₋₄ alkyl or NR¹⁵R¹⁶; and R¹⁵ and R¹⁶ are each independently H, C₁₋₄alkyl, C₁₋₄alkylcycloalkyl, C₁₋₄alkylcyclohetalkyl, aryl or hetaryl, or may be joined to form a 3-8 membered ring optionally containing an atom selected from O, S or NR¹⁷; and R¹⁷ is selected from H or C₁₋₄alkyl; and prodrugs are esters of a free carboxyl or hydroxy group or amides of a free amino group.”---

In claim 3, the entire text:

A compound according to claim 1 wherein W is C₂₋₄alkyl or C₁₋₄alkylamino which is a mixture of the compound that possesses S chirality at the chiral carbon bearing W, and the compound that possesses R chirality at said carbon.

has been deleted and replaced with the following:

---“A compound according to claim 1 wherein W is C₂₋₄alkyl or C₂₋₄alkylamino which is a mixture of the compound that possesses S chirality at the chiral carbon bearing W, and the compound that possesses R chirality at said carbon.”---

In claim 9, the text of lines 1 and 2:

A compound according to claim 1, wherein the compound is selected from the group consisting of:

has been deleted and replaced with the following:

---“A compound selected from the group consisting of:”---

In claim 9, the text of the last line:

and the salts and stereoisomers thereof.

has been deleted and replaced with the following:

---“and the pharmaceutically acceptable salts and stereoisomers thereof.”---

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In claim 15, the entire text:

A method of modulating microtubule polymerization in a cell which method comprises administering a compound according to claim 1.

has been deleted and replaced with the following:

---“A method of modulating microtubule polymerization in a cell wherein said method comprises administering a compound according to claim 1.”---

In claim 16, the entire text:

A method of modulating microtubule polymerization in a cell which method comprises administering a compound according to claim 2.

has been deleted and replaced with the following:

---“A method of modulating microtubule polymerization in a cell wherein said method comprises administering a compound according to claim 2.”---

Claims 11-13 and 17 have been cancelled.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Kate H. Murashige (Reg. No. 29,959) on January 28, 2011.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DOUGLAS M. WILLIS, whose telephone number is 571-270-5757. The examiner can normally be reached on Monday thru Thursday from 8:00-6:00 EST. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached on 571-272-0661. The fax phone number for

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the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DOUGLAS M WILLIS/
Examiner, Art Unit 1624

**/James O. Wilson/
Supervisory Patent Examiner, AU 1624**